April 12, 2007

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Management Dockets, N/A
Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1-23
12420 Parklawn Dr
Rockville, MD 20857

Re: General Correspondence: Comments on Draft Guidance for Industry, 'Advisory Committee Meetings - Preparation and Public Availability of Information Given to Advisory Committee Members' Federal Register Volume 72, No. 39, Page 9008 [Docket No. 2007D-0021]

Dear Sir or Madam:

Reference is made to the notice published by the Food and Drug Administration in the Federal Register on February 27, 2007 announcing the availability of the draft guidance for comment entitled '*Advisory Committee Meetings - Preparation and Public Availability of Information Given to Advisory Committee Members*'.

GlaxoSmithKline is a research-based pharmaceutical and biotechnology company dedicated to the discovery, development, manufacture and distribution of medicines and vaccines that enable people to lead longer, healthier and more productive lives. We appreciate the opportunity to comment on this draft guidance and provide the following comments:

1. Page 6, Section III. B., Second paragraph

The order of the first three sentences of this paragraph is rather confusing and seems to imply that sponsors who submit fully releasable materials may have their materials posted sooner than those who assert that portions of their materials are exempt. This may create a disincentive for sponsors to submit 'fully releasable' packages in good time and create additional redaction work for the Agency.

We suggest the following alternative wording:

> "If a sponsor prepares briefing materials for an advisory committee meeting on a pending application, they will be posted on our website in advance of the meeting. The promptness of posting to the website will not be affected by the sponsor's choice to a) submit materials that are fully releasable without redaction or b) submit materials that the sponsor asserts is exempt from disclosure under FOIA and thus require redaction. However, this choice does have an impact on when the sponsor must submit the materials to the Agency – see Appendices."

2. Page 7, Section III. B., Third paragraph

We assert that both the FDA and sponsor materials relating to a particular drug discussion should be posted on the same day. If two drugs are to be discussed over a two day advisory committee meeting and they are for a related indication or class, we suggest that all materials should be made publicly available at the same time, at least two business days before the meeting.

3. Page 8, Section IV. A., Line 7

Additional guidance is sought about the appropriate method for managing electronic documents that represent Briefing Materials for Advisory Committee meetings for applications that are managed in eCTD format. Is it the Agency's intent that these should be submitted to the XML backbone and associated with m1.6.2?

4. Appendix A

Consistent with Section IV.A; Appendix B states that 55 business days before the meeting, the Agency will notify the sponsor that it intends to take an issue to an Advisory Committee; we suggest that this 'start date' also be included in Appendix A covering the more common scenario where materials are fully releasable.

5. Appendix A

In Appendix A the column titled "FDA Action", it stipulates that FDA will provide Advisory Committee members with copies of the Agency's unredacted briefing materials, sometime between business days 21 through 14 before the meeting; however it does not specifically state that FDA will similarly provide the committee with the sponsor's briefing materials, or when that will occur--this should be identified in this Appendix.

Thank you for this opportunity to comment on this important draft guidance. This submission is provided in electronic format according to the instructions provided at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm.

If there are any questions about this submission or our comments, please contact me at (919) 483-5121 or my colleague Anne Stokley at (919) 483-6405. Thank you.

Sincerely,

Lorna C Wilson

Lorna C. Wilson
Director, US Regulatory Affairs